

AUG 16 2004

K031714 page 1/2



510(k) SUMMARY

for the Inion Trinion™ Biodegradable Meniscus Screw

MANUFACTURER

Inion Ltd.
Lääkärintäti 2
FIN-33520 Tampere

Contact Person:
Hanna Marttila
Regulatory Affairs Manager
Lääkärintäti 2
FIN-33520 Tampere
Phone: +358 3 2306 600
Fax: +358 3 2306 601
Hanna.Marttila@Inion.fi

DEVICE NAME

Trade name: Inion Trinion™ Biodegradable Meniscus Screw
Common/Usual Name: Biodegradable Meniscal Screw

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

Classification panel: Orthopedic
Regulatory Class: Class II, MAI

PREDICATE DEVICES

Innovative Devices, Inc.; Innovative Meniscal Screw (K980681) Mitek Clearfix
Biomet, Inc.; LactoSorb Meniscal Screw (K002020)
Linvatec Corp.; BioStinger –V Bioabsorbable Meniscal Repair Device (K991715)
Bioscience, Inc.; Biofix Biodegradable Meniscus Arrow System (K955768)

Date: 15.5.2003
Status: Final

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion Trinion™ Biodegradable Meniscus Screw is intended for use in the fixation of longitudinal vertical meniscus lesions (bucket handle) located in the vascularized area of the meniscus (red-red and red-white areas). Screws are offered in different lengths typical for this application. The system will be provided sterile to the user and is not to be re-sterilized. The Inion Trinion™ Biodegradable Meniscus Screw is designed to be used with customized instrumentation.

The Inion Trinion™ Biodegradable Screw is made of resorbable polylactic acid / trimethylenecarbonate copolymers [Poly (L-lactide-co-D,L-lactide) and poly (L-lactide-co-trimethylenecarbonate)]. The Inion Trinion™ Biodegradable Meniscus Screws are offered both undyed and coloured for better visualization during surgical operation. The Trinion™ Biodegradable Meniscus Screw gradually loses its strength during 18-36 weeks. Bioresorption takes place within two to three years.

EQUIVALENCE TO MARKETING PRODUCTS

The properties of the Inion Trinion™ Biodegradable Meniscus Screw are substantially equivalent to those of the previously accepted and clinically successfully used biodegradable meniscal repair devices.

Inion Trinion™ Biodegradable Meniscus Screw, Innovasive Meniscal Screw (Mitek Clearfix), LactoSorb Meniscal Screw, BioStinger –V Bioabsorbable Meniscal Repair Device and Biofix Biodegradable Meniscus Arrow System have the same intended use and principles of operation and very similar design characteristics. Biomechanical testing demonstrates that the device is substantially equivalent to the predicate ones. Differences between The Inion Trinion™ Biodegradable Meniscus Screw and predicate devices do not raise new questions of safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2004

Ms. Hanna Marttila
Regulatory Affairs Manager
Inion Ltd.
Lääkärintäti 2
FIN-33520 Tampere
Finland

Re: K031714
Trade/Device Name: Inion Trinion™ Biodegradable Meniscus Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 27, 2004
Received: June 1, 2004

Dear Ms. Marttila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

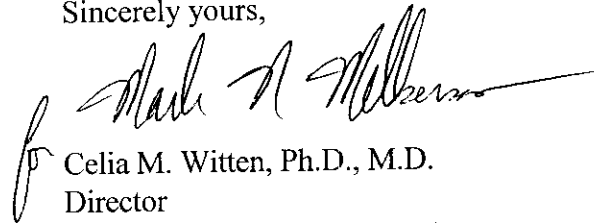
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Hanna Marttila

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a **legally** marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over a horizontal line.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K031714

Device Name: **Inion Trinion™ Biodegradable Meniscus Screw**

Indications:

The Inion Trinion™ Biodegradable Meniscus Screw is indicated for use in the fixation of longitudinal vertical meniscus lesions (bucket handle) located in the vascularized area of the meniscus (red-red and red-white areas).

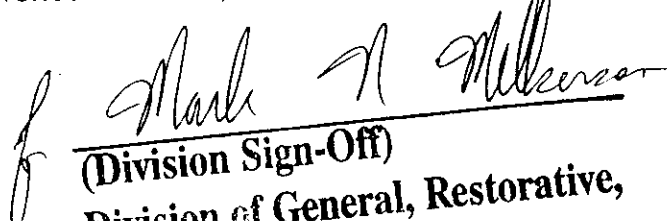
Prescription Use 3rd
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K031714

Page 1 of ____